

Remarks

Claims 28-30 and 42-49 are pending in the application and subject to an election of species requirement.

The Office action alleges that the claims are directed to more than one species of generic invention of claim 28. For the method of screening candidate compounds of claim 28, the Office requires election of a species of subunit of dimeric form of interleukin where the subunit is selected from the group of subunits listed in claim 42, and further requires election of a cell line according to claim 43 or 44.

Applicants elect, as the species of subunit form, the p40 (beta) subunit IL-12. Applicants elect the cell line according to claim 43. The election is made with traverse. The claims that read on the elected species are 28-30, 42, 43 and 45-49.

The claims present a unified single inventive concept which defines a contribution over the prior art. The election of species requirement is not provided for, and therefore contravenes, PCT Rule 13. Indeed, Rule 13.4 provides that applicant shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, *even where the features of any dependent claim could be considered as constituting in themselves an invention.*

Moreover, the election of species requirement is improper because Examiner has failed to sustain the evidentiary burden of demonstrating that the species of invention are not so linked to form a single general inventive concept under PCT Rule 13.1. Indeed, no evidence whatsoever is provided. Examiner merely alleges, with no further elaboration that, the species presented in the dependent claims “are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.”

Unity of invention under PCT Rule 13 and 37 C.F.R. 1.475 is satisfied when there is a technical relationship among those inventions defined by the claims which involves “one or more of the same or corresponding special technical features.” This unifying special technical feature is that which defines a contribution which each of the claimed inventions, considered as a

whole, makes over the prior art. PCT Rule 13.2 and the PCT Administrative Instructions, Annex B, Part 1(b).

The burden for demonstrating lack of unity under PCT Rule 13 and 37 C.F.R. 1.475 is on the Office. The instant office action advances no basis for finding that the claims fail to share one or more of the same or corresponding special technical features pursuant to PCT Rule 13.2. The office action points to no prior art that would show that the claims as presently pending fail to define an inventive contribution. In the absence of such a finding, the election of species requirement must be withdrawn.

While it is not applicants' burden to identify a common special technical feature shared by the species of claim 42, that relationship does in fact exist. The inventors have determined a method of expressing DNA encoding a dimeric form of interleukin where the method can further include the step of screening candidate compounds for the ability to inhibit assembly and secretion of dimeric forms of interleukin wherein, in order to screen candidate compounds for the ability to inhibit assembly and secretion of dimeric forms of interleukin. The method allows the interleukin to be correctly post translationally processed, for example, to be correctly folded and to be secreted without perturbation in the absence of the candidate compounds being screened.

As outlined at page 58 of the published application, the use of an expression vector wherein the interleukin is under transcriptional control of the ecdysone promoter is advantageous over the use of natural producer cells of interleukin, as natural producer cells do not reproducibly produce dimeric interleukin, and dimeric interleukin is typically only provided in restricted amounts.

The invention of claim 28 recites a unifying special technical feature that defines a contribution over the state of the art. In the absence of any contrary finding, supported by evidence, the election of species requirement must be withdrawn.

Applicants reserve the right to respond to any future action by the Examiner finding lack of unity.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'D. Monaco', is written over a horizontal line.

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